

REMARKS**I. Status of the Application**

Claims 1 and 31-37 were pending prior to this response. The Examiner has withdrawn claim 37 as she felt it was not consistent with the elected species. Applicant has added new claims 55 and 56 with this response. New claims 55 and 56 also do not present new matter. Support for the addition of claim 55 can be found in the specification at least at page 6, lns. 1-20; page 9, lns. 21-22; page 10, lns. 20-25; page 12, lns. 5-9; page 17, lns 15-20; page 18, lns 15-20; and page 21, lns. 12-18. Support for the addition of claim 56 can be found in the specification at least at page 6, lns. 1-20; page 9, lns. 21-22; page 10, lns. 20-25; page 12, lns. 5-9; page 17, lns 15-20; page 18, lns 15-20; and page 21, lns. 12-18. Accordingly, claims 1, 31-36, 55, and 56 are currently pending before the Examiner.

Of the pending claims, the Examiner has rejected claim 1 under 35 U.S.C § 102(b) as being anticipated by U.S. Patent No. 5,413,120 (hereinafter “Grant”). The Examiner has also rejected claims 1 and 31-36 under 35 U.S.C. § 103(a) as being unpatentable under U.S. Patent No. 5,076,289 (hereinafter “Darling”) in view of Grant. Finally, the Examiner rejected claims 1, 31, 34, 35, and 36 under the judicially created doctrine of double patenting as being unpatentable over claims 1, 3, 12, and 23 of U.S. Patent No. 6,526,981 (hereinafter “Rozier”). As explained below, Applicants respectfully traverse all of these rejections and request withdrawal of the same.

The Examiner also made two other objections in her June 2, 2004 Office Action. First, the Examiner pointed out that publications dates for citations 17 and 18 of Applicants' Information Disclosure Statement (“IDS”) were not provided when the IDS was filed on April 23, 2002. Second, the Examiner objected to Applicants' drawings, explaining that the drawings failed to comply with 37 C.F.R. § 1.84(p)(5) as they did not include the reference sign, “element

31.” As explained below, Applicants also respectfully traverse these objections and request withdrawal of the same.

II. Rejection under 35 U.S.C. § 102(b)

Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Grant. However, Grant does not disclose each and every element of claim 1.

Claim 1 discloses a site guard, for use on any portion of a patient’s body, comprising a hollow member and a fabric connector. Specifically, the hollow member disclosed in claim 1 comprises a base with an edge to be positioned upon a patient adjacent a site, the base having a width sufficient to straddle the site and a length and a height sufficient to cover the site, the base joined to a sidewall to form a cover. Moreover, the fabric connector, as disclosed in claim 1, is affixed to the hollow member in order to hold the site guard in place over the site.

In contrast, Grant discloses a catheter shield for use on a patient’s hand or wrist, comprising “a base and an overlying transparent shield.” (Col. 2, lns. 51-53). Particularly, the “base” disclosed by Grant is a “base member dimensioned to underlie a patient’s hand or wrist.” (Col. 2, lns. 5-9). This base contains “open slots” or “strap receiving slots” through which straps can be inserted to secure the patient’s hand to the base. (Col. 3, lns 5-9). Furthermore, Grant discloses a transparent shield which rests on top of the base and covers the site. (Col. 3, lns. 29-45).

Consequently, Grant cannot anticipate claim 1 because Grant does not disclose a hollow member with a base having an edge to be positioned upon the body part of a patient adjacent a site. Rather, Grant discloses a base, which is positioned under a patient’s wrist or arm. Moreover, Grant does not disclose a hollow member that is affixed to a fabric connector. Instead, Grant discloses a base, which contains open slots to accommodate straps. Furthermore,

unlike the site guard disclosed in claim 1, the straps in Grant hold only the base to the patient, and not the entire site guard to the patient.

Accordingly, Applicants respectfully submit that claim 1 is allowable over Grant. It follows that claims 31-36 are also allowable as they depend on claim 1.

III. Rejection under 35 U.S.C. § 103(a)

As set forth above, claims 1 and 31-36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Darling in view of Grant. However, it is respectfully submitted that the Examiner has failed to make a *prima facie* case of obviousness with regard to claims 1 and 31-36 because neither Darling nor Grant, alone or in combination, disclose or suggest the presently claimed invention.

The Pending Application discloses a multi-purpose site guard for use on all types of patients at all peripheral and central vein puncture infusion sites and sensitive areas. Further, the site guard disclosed in the Pending Application comprises two basic components, a hollow member and a fabric connector. The hollow member comprises a base with an edge to be positioned upon a patient adjacent a site, the base having a width sufficient to straddle the site and a length and a height sufficient to cover the site, the base joined to a sidewall to form a cover. In addition, affixed to the hollow member is a fabric connector which holds the site guard in place over the site.

In contrast, Darling discloses a means of supporting the attachment of an intravenous (“I.V.”) line to a patient. (Col. 1, Ins. 5-9). Specifically, Darling discloses a support means with one basic component, “an integral fabric wrap.” (Col. 3, Ins. 48-53 and Fig. 1). For the support means to function, the I.V. line is looped around a patient’s thumb, the patient’s thumb is

inserted through a slit in the support means, and the support means is then wrapped around the patient's hand. (Col. 3, lns. 38-54).

Consequently, Darling does not teach or suggest the Pending Application. Darling does not teach or suggest a site guard comprising a hollow member and a fabric connector. Darling also does not teach or suggest the use of a site guard on any portion of a patient's body. Nor, does Darling teach or suggest a device which covers infusion sites or sensitive areas. Darling only teaches and suggests a device that is directed at attaching an I.V. line to a patient. In light of the above, claim 1 is allowable as the site guard disclosed in the Pending Application is not obvious under Darling.

The site guard disclosed in the Pending Application is also not obvious even when Darling is combined with Grant. Nothing in Grant teaches or suggests a hollow member with a base having an edge to be positioned upon the body part of a patient adjacent a site. Moreover, Grant does not teach or suggest a hollow member that is affixed to a fabric connector. Instead, Grant discloses a base which contains open slots to accommodate straps. Furthermore, unlike the site guard disclosed in the Pending Application, the straps in Grant hold only the base to the patient, and not the entire site guard to the patient. For all of the aforementioned reasons, the Pending Application is not obvious even if Darling is combined with Grant. Thus, claim 1 is allowable.

There is, however, no suggestion to combine these references. In addition, even if one skilled in the art combined Darling with Grant, such a combination would not achieve the same results as the Pending Application. Consequently, because a combination of Darling and Grant does not render obvious the site guard disclosed in the Pending Application, claim 1 is allowable. Claims 31-36 are also not obvious and are allowable as they depend on claim 1.

IV. Rejections under the Judicially Created Doctrine of Obviousness-Type Double Patenting

The Office rejected claims 1, 31, 34, 35, and 36 under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1, 3, 12, and 23 of Rozier. This rejection is respectfully traversed as Applicants have taken the Office's advice and submitted with this Amendment a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c). Consequently, Applicants respectfully ask that the Office withdraw this rejection.

V. Information Disclosure Statement

The Examiner pointed out that publication dates for citations 17 and 18 of Applicants' IDS were not provided when the IDS was filed on April 23, 2002. Applicants apologize for this accidental omission and remedy their omission by providing the Examiner with the publication dates for these two citations. The publication date for citation 17 entitled, "I.V. House Brochure – 'Protection Over and Above,'" was January 2002. The publication date for citation 18 entitled, "I.V. House Key Brochure – 'Introducing the Master Key to IV Safety and Cost Control,'" was September 2001. Because Applicants have now provided the Examiner with the publication dates for citations 17 and 18, Applicants ask that the Examiner initial these references on the IDS.

VI. Drawing

The Examiner objected to the Applicants' drawings, explaining that the drawings failed to comply with 37 C.F.R. § 1.84(p)(5) as they do not include the reference sign, "element 31," which is mentioned in the description. The Examiner correctly states that the description mentions element 31. However, Applicants respectfully point out that their drawings, as originally filed, do include references to element 31. Specifically, Figures 4a, 4b, 4c, 7a, 7c, and

19 include references to element 31. Therefore, because Applicants' drawings do contain reference signs to element 31, Applicants request withdrawal of this objection.

VII. New Claims

Applicant is adding new claim 55. Applicant believes that new claim 55 is allowable as neither Darling nor Grant, alone or in combination, teach or suggest a site guard comprising a hollow member and a fabric connector, wherein the connector is capable of holding the hollow member in place without the need for any adhesive. Therefore, Applicant believes that claim 55 is allowable.

Applicant is also adding new claim 56. Applicant believes that new claim 56 is allowable as neither Darling nor Grant, alone or in combination, teach or suggest a site guard comprising a hollow member and a fabric connector having a first end and a second end, the first end affixed to the edge of the hollow member, the second end having a closure means wherein the connector is capable of holding the hollow member in place without the need for any adhesive. Therefore, Applicant believes that claim 56 is also allowable.

VIII. Conclusion

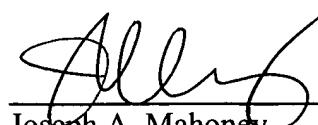
With entry of the above amendment and in view of the foregoing remarks, it is respectfully submitted that claims 1, 31-36, 55 and 56 are in condition for allowance.

None of Applicant's amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicants reserve all rights to pursue any such subject matter in this or a related patent application.

It is respectfully submitted, in view of the foregoing Amendment and Remarks, that all of the objections and rejections in the Office Action dated June 2, 2004 have been overcome and should be withdrawn. Applicant respectfully requests early and favorable notification to that

effect. The Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution

Respectfully submitted,



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